APR 0 3 2002

510(k) Summary

K 012221

1) Submitter's Name Address, contact

BIOSAFE Laboratories, Inc.
100 Field Drive, Suite 240
Lake Forest, IL 60045

Phone: (847) 234-8111
FAX: (847) 234-8222

Contact Person: Jack A. Maggiore, PhD
BIOSAFE Laboratories, Inc.
(773) 693-0400, x253

Date Prepared: September 6, 2001

2) Device Name

Proprietary Name: SAFE AT HOME CHOLESTEROL PROFILE Blood Collection and Transport System

Common Name: At-home capillary blood self-collection and transportation system for Total Cholesterol, HDL-Cholesterol, Triglycerides and Calculated LDL-Cholesterol

Classification Names: Cholesterol (21 CFR 862.1175)
HDL-Cholesterol (21 CFR 862.1475)
Triglycerides (21 CFR 862.1705)
LDL-Cholesterol (21 CFR 862.1475)

3) Predicate Devices

Total Cholesterol	Beckman Synchron Synchron CX Systems Cholesterol (CHOL) Reagent (K974046)
HDL Cholesterol	Sigma EZ HDL™ Cholesterol Reagent (K972041)
Triglycerides	Beckman Triglycerides Reagent Kit (K781939)

4) Device Description

The device is a kit containing the materials necessary to self-collect a capillary blood sample onto a filter paper card for transport to a certified clinical laboratory for lipid profile testing. The kit is comprised of a blood collection card packaged in a foil pouch, alcohol prep pad, disposable lancets, gauze pad, bandage strip, collection instructions, return prepaid envelope, and a patient test authorization form.

5) Intended Use

The SAFE AT HOME CHOLESTEROL PROFILE Blood Collection and Transport System is intended for over-the-counter distribution, for the self-collection and transportation of dried capillary blood for *in vitro* diagnostic quantitative determination of Total Cholesterol, HDL-Cholesterol, Triglycerides and Calculated LDL-Cholesterol in dried blood spots. This kit is not intended for use on neonates. LDL cannot be determined where the triglyceride value is greater than 400 mg/dL.

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510(k) Summary, *continued*

6) Comparison to predicate device	The SAFE AT HOME CHOLESTEROL PROFILE Blood Collection and Transport System has technological characteristics that are substantially equivalent to that of the predicate devices listed above. The SAFE AT HOME CHOLESTEROL PROFILE Blood Collection and Transport System provides components that permit collection, storage, and transportation of a dried capillary blood sample to a certified clinical laboratory for analysis using FDA-Approved laboratory reagent and analysis systems. All predicate and current kits are intended for the *in vitro* diagnostic laboratory determination of lipid profile analytes. The laboratory analyses used in conjunction with (accessories of) the SAFE AT HOME CHOLESTEROL PROFILE Blood Collection and Transport System, utilize the Synermed Cholesterol Reagent Kit (K903015), Sigma Diagnostics Infinity Triglyceride Reagents (K844032), and Sigma Diagnostics EZ-HDL Cholesterol Reagents (K972041). Results of clinical trials show that self-collected capillary samples onto the BIOSAFE Blood Collection Card provide results that are substantially equivalent to venous (serum) results for Total Cholesterol, HDL-Cholesterol and Triglycerides when analyzed using BIOSAFE Laboratories modified analytical methods.
7) Performance Studies	Determination of self-collected capillary blood Total Cholesterol, HDL Cholesterol and Triglycerides using the SAFE AT HOME CHOLESTEROL PROFILE Blood Collection and Transport System is substantially equivalent to venous (serum) samples for lipid profile testing BIOSAFE Laboratories modified analytical methods. Performance studies were conducted on self-collected capillary blood samples from volunteer study subjects at three different geographical sites. A corresponding venous blood sample and a professionally collected capillary blood sample were collected by the health care professional in order to compare serum lipid results to those obtained from both capillary blood samples collected onto the BIOSAFE Blood Collection Card. Venous samples were express shipped, and dried capillary samples were mailed directly to BIOSAFE Laboratories for lipid profile analysis by their respective methods.
8) Test Summary	Performance characteristics studied included precision, total error and correlation. In addition, the SAFE AT HOME CHOLESTEROL PROFILE Blood Collection and Transport System was evaluated for sample stability when exposed to abusive storage and transportation conditions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Jack Maggiore, Ph.D.
Director, Clinical Trials
BIOSAFE Laboratories, Inc.
100 Field Drive - Suite 240
Lake Forest, IL 60045

APR 0 3 2002

Re: k012221
Trade/Device Name: Safe At Home Cholesterol Profile
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood specimen collection device
Regulatory Class: Class II
Product Code: JKA
Dated: March 6, 2002
Received: March 7, 2002

Dear Dr. Maggiore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

C. Indications for Use Statement

The SAFE AT HOME CHOLESTEROL PROFILE Blood Collection and Transport System is intended for over-the-counter distribution, for the self-collection and transportation of dried capillary blood for *in vitro* diagnostic quantitative determination of Total Cholesterol, HDL-Cholesterol, Triglycerides and Calculated LDL-Cholesterol in dried blood spots. This kit is not intended for use on neonates. LDL cannot be determined where the triglyceride value is greater than 400 mg/dL.

Alberto Gutierrez for Kaiser Azi...

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012221

Over the counter use ✓